



CMS-1635-N

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1635-N]

Medicare, Medicaid, and Children's Health Insurance Programs; Advisory Panel on Clinical Diagnostic Laboratory Tests and Request for Nominations

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the establishment of an Advisory Panel on Clinical Diagnostic Laboratory Tests (the Panel) and requests nominations for individuals to serve on the Panel.

DATES: Nominations will be considered if we receive them at the appropriate address, provided in the "**ADDRESSES**" section of this notice, no later than 5 p.m., e.d.t. on **[PLEASE INSERT 30 DAYS AFTER DATE OF PUBLICATION]**.

ADDRESSES: Mail or deliver written nominations for membership to the following address: Glenn C. McGuirk, Designated Federal Official, Center for Medicare, Division of Ambulatory Services, CMS, 7500 Security Boulevard, Mail Stop C4-01-26, Baltimore, MD 21244, or e-mail to Glenn.McGuirk@cms.hhs.gov.

FOR FURTHER INFORMATION CONTACT: Glenn C. McGuirk, 410-786-5723, e-mail Glenn.McGuirk@cms.hhs.gov, or visit the website <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html?redirect=/ClinicalLabFeeSched/>.

Press inquiries are handled through the CMS Press Office at (202) 690-6145.

SUPPLEMENTARY INFORMATION:

I. Background

The Advisory Panel on Clinical Diagnostic Laboratory Tests is authorized by section 1834A(f)(1) of the Social Security Act (the Act) (42 U.S.C. 1395m-1), as established by section 216 of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub L. 113-93, enacted April 1, 2014), and is subject to the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory panels.

II. Provisions of this Notice

A. Objectives and Scope of the Panel

Section 1834A of the Act requires the establishment of new Medicare payment rates for clinical diagnostic laboratory tests furnished on or after January 1, 2017, based on private payor rates, and establishes processes for determining initial payments for new clinical diagnostic laboratory tests (including advanced diagnostic laboratory tests). As set forth in section 1834A(f)(1) of the Act, the Secretary of Health and Human Services (the Secretary) will consult with an expert outside advisory panel, to be established by the Secretary not later than July 1, 2015, composed of an appropriate selection of individuals with expertise in issues related to clinical diagnostic laboratory tests. Such individuals may include representatives of clinical laboratories, molecular pathologists, clinical laboratory researchers, and individuals with expertise in clinical laboratory science or economics of clinical laboratory services. The Panel will provide input to the Secretary and the Administrator of the Centers for Medicare & Medicaid Services (CMS) on the following:

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- The establishment of payment rates under section 1834A of the Act for new clinical diagnostic laboratory tests, including whether to use crosswalking or gapfilling processes to determine payment for a specific new test; and
- The factors used in determining coverage and payment processes for new clinical diagnostic laboratory tests.

In addition, the Panel will provide recommendations to the Secretary and the Administrator of CMS under section 1834A of the Act.

B. Description of Duties

The Panel will provide input and recommendations on the following issues:

- Calculation of weighted median for laboratory services using private payor rates.
- Phase-in of reductions from private payor rate implementation.
- Application of market rates.
- Evaluation and designation of tests as advanced diagnostic laboratory tests.
- Whether to use crosswalking or gapfilling to determine payment for a specific new test.
- The factors used in determining coverage or payment processes for new clinical diagnostic laboratory tests.

The subject matter before the Panel will be limited to these and related topics. Unrelated topics will not be subjects for discussion. Unrelated topics will include, but are not limited to, definition of an applicable laboratory for purposes of reporting private payor data, definition of a data collection period, treatment of discounts, reporting of more than one payment rate for the same payor, certification of data, definition of a private payor, civil monetary penalties for

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noncompliance with reporting requirements, and generally, Medicare conditions of payment for clinical diagnostic laboratory tests.

Panel meetings will be held up to 4 times a year. The Panel will consist of up to 15 individuals and a Chair. The Panel Chair will be a federal official who is designated by the Secretary or the Administrator of CMS. The Panel Chair will facilitate meetings and the Designated Federal Officer (DFO) or designee must be present at all meetings. Meetings will be open to the public except as determined otherwise by the Secretary or other official to whom the authority has been delegated in accordance with the Government in the Sunshine Act of 1976 (5 U.S.C. 552b(c)) and FACA. Notice of all meetings will be published in the **Federal Register** as required by applicable laws and Departmental regulations. Meetings will be conducted, and records of the proceedings kept, as required by applicable laws and departmental regulations.

To conduct the business of the Panel, a quorum is required. A quorum exists when a majority of currently appointed members is present at full Panel or subcommittee meetings or is participating in conference calls.

Unless renewed by appropriate action prior to expiration, the Panel will terminate 2 years from the filing date of its charter.

C. Request for Nominations

We are requesting nominations for members to serve on the Panel. As noted previously, the Panel will consist of up to 15 individuals with expertise in issues related to clinical diagnostic laboratory tests, which may include representatives of clinical laboratories, molecular pathologists, clinical laboratory researchers, and individuals with expertise in clinical laboratory science or economics of clinical laboratory services. Such issues may include the development,

validation, performance, safety, and application of such tests. Nominees must demonstrate personal experience with clinical laboratory tests and services through a past or present history of direct employment with an organization that furnishes clinical diagnostic laboratory tests, or in an academic or research capacity. For purposes of this Panel, consultants or independent contractors are not considered to be representatives of clinical laboratories.

All members will serve on a voluntary basis, without compensation, pursuant to advance written agreement. Members of the Panel will be entitled to receive reimbursement for travel expenses and per diem in lieu of subsistence expenses, in accordance with standard Federal Travel Regulations. A member may serve after the expiration of his/her term until a successor has been sworn in.

The nominees will be evaluated based on expertise and factors needed to maintain a balance of representation on the Panel. These factors include, but are not limited to, geographic area representation, female and minority representation, points of view, and areas of expertise (for example, medical, scientific, financial, technical, or administrative). In addition, all nominees must have at least 5 years of experience with clinical diagnostic laboratory tests or genetic testing.

Nominations will be considered from all geographic locations within the United States or its territories. Any organization or person may nominate one or more qualified individuals for Panel membership. Self-nominations will also be accepted.

Each nomination must state that the nominee has expressed a willingness to serve as a Panel member and must be accompanied by a curriculum vitae and a brief biographical summary of the nominee's experience. All curricula vitae must include the following:

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- Title and current position.
- Professional affiliation.
- Home and business address.
- Telephone and fax numbers.
- E-mail address.
- List of areas of expertise.

In addition, each nomination letter must include the reasons why the nominee should be considered, as well as a written and signed statement that the nominee is willing to serve on the Panel under the conditions described in the notice and further specified in the Charter.

The top nominees will be contacted in regard to their interest and availability. Phone interviews of nominees may also be requested after review of the nominations. The CMS Administrator or designee will make the final decision about who will serve on the Panel. Formal letters of invitation to serve on the Panel will be extended by the CMS Administrator.

To permit an evaluation of possible sources of conflict of interest, potential candidates will be asked to provide detailed information concerning such matters as financial holdings, consultancies, and research grants or contracts.

The selected candidates will be invited to serve for a term of up to 3 years, contingent upon the renewal of the Panel by appropriate action prior to its termination. A member may serve after the expiration of that member's term until a successor takes office. Any member appointed to fill a vacancy for an unexpired term will be appointed for the remainder of that term.

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III. Copies of the Charter

The Secretary's Charter for the Advisory Panel on Clinical Diagnostic Laboratory Tests is available on the CMS website at <http://www.cms.gov/FACA/XXXXXXX.asp>, or you may obtain a copy of the charter by submitting a request to the contact listed in the **FOR FURTHER INFORMATION** section of this notice.

Dated: October 21, 2014.

Marilyn Tavenner,
Administrator,
Centers for Medicare & Medicaid
Services.

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